

DEC 22 2004

K042760

510(k) SUMMARY

Pefakit® APC-R Factor V Leiden Controls

In accordance with the requirements of Safe Medical Devices Act (SMDA) of 1990, a 510(k) summary is provided as outlined in 21 CFR 807.92.

Part A

1. Submitter's name, address, telephone number, contact person, and the date the summary was prepared

Submitter's Name:	Pentapharm Ltd.
Submitter's Address:	Engelgasse 109 CH-4002 Basel/Switzerland
Submitter's Telephone Number:	++41 61 706 48 48
Submitter's Contact:	Reto Schöni, PhD Regulatory Affairs Specialist Diagnostics, R&D Hemostasis and Test Kit Development
Date of 510(k) Preparation:	September 30, 2004

2. Name of the device, including the trade or proprietary name, the common or usual name and the classification name

Trade or Proprietary Name:	Pefakit® APC-R Factor V Leiden Controls
Common or Usual Name:	Quality Control Plasmas
Classification Name:	Hematology, Factor deficiency test

3. Identification of the legally marketed device to which the submitter claims substantial equivalence

Predicate Device Name:	COATEST® APC™ RESISTANCE V / COATEST® APC™ RESISTANCE VS
510(k) Number:	K963111
Regulation Number:	864.7925
Regulatory Class:	II

4. Description of the device

Pefakit® APC-R Factor V Leiden Controls is an in vitro diagnostic controls kit containing 3 vials each of the following 2 lyophilized plasmas:

C1: pooled human plasma from donors confirmed to be normal wild-type by FV Leiden PCR testing

C2: pooled human plasma from donors confirmed to be heterozygous by FV Leiden PCR testing.

5. Statement on the intended use of the device

The device is a kit containing pooled plasmas from donors genotyped for the factor V Leiden mutation (FV:Q506). Controls contain pooled plasmas of either donors with heterozygous FV:Q506 mutation or normal wild-type pattern. These controls are intended to be used in connection with the device Pefakit® APC-R Factor V Leiden.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device

The predicate device COATEST® APC™ RESISTANCE V / COATEST® APC™ RESISTANCE VS contains plasmas of the FV-L wild-type/normal (level 1) and FV-L heterozygous (level 2) type as controls. They are an integrated part of this test device. For 'Pefakit® APC-R Factor V Leiden' the controls are offered as a separate kit named 'Pefakit® APC-R Factor V Leiden Controls', being object of the present submission. Unlike calibrators which normally represent a quantitative property of the analyte these controls stand for a qualitative property (genotype) of the analyte. Controls for FV-L APC resistance testing in general are used to verify that the clotting time and ratio values obtained for the different FV-L genotypes remain within a predefined range established for the specific laboratory and a specific instrument. They are thus used for quality control and for validation of the basic test reagents before and/or after each test run.

With respect to material, presentation, purpose, safety, preparation and handling the lyophilized plasmas C1 (FV-L Negative Control) and C2 (FV-L Heterozygous Control) controls are substantially equivalent to level 1 and level 2 control plasmas of the predicate device. The different ranges of expected values are a result of differences in the test principle between the two basic tests.

The material of both devices compared is derived from pooled human plasma genotyped with an approved PCR test specific for the Factor V Leiden mutation. It has been screened for absence of viruses (HIV1&2, HCV, HBV, and HTLV I&II) by FDA-approved methods. Since no screening layout can completely rule out the presence of blood borne diseases, both devices carry the warning information, that the material is derived from human blood and has therefore to be handled as potentially infectious material.

Part B

1. Brief discussion of the non-clinical tests submitted, referenced , or relied on in the premarket notification submission for a determination of substantial equivalence

Non-clinical tests were done in-house to determine stability and batch-to-batch variability. The control plasmas have shown to be very stable under different conditions relevant for their use and storage. On-board stability of the reconstituted controls is at least 8h which is equivalent or even superior to what has been claimed for the predicate device. Reconstituted and frozen plasmas are stable at -20°C for at least 6 months, compared to 3 months for the controls in the predicate device. Real time long-term stability studies for the kit and its control plasmas are still ongoing, but so far the kit proved to be stable for 2 years when stored unopened at 2-8°C.

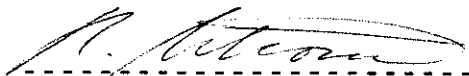
Batch-to-batch variability has been demonstrated to be very low on three pilot batches of increasing size (100, 250, and 1000 device boxes) of both the basic device and the control device.

2. Brief discussion of the clinical tests submitted, referenced or relied on in the premarket notification submission for a determination of substantial equivalence

The Pefakit® APC-R Factor V Leiden was compared side-by-side with the predicate device COATEST® APC™ RESISTANCE V in clinical studies at two haematology laboratories of big central Hospitals in Europe (Clinical Institute for Medical and Chemical Laboratory Diagnostics/Allgemeines Krankenhaus [CIMCLD/AKH], Vienna) and the USA (Duke University Medical Center [DUMC], Durham/Raleigh NC). The results of these studies have been given and discussed in a separate 510(k) submission for the basic test device. The respective controls have been used in these studies for quality control and reagent validation. The Pefakit® control plasmas proved to be suitable for their intended use and to be equivalent to the control plasmas in the predicate device.

3. Conclusions drawn from the non-clinical and clinical tests that demonstrate that the device is as safe, as effective, and as well or better than the legally marketed device identified in part A (3)

The control plasmas of 'Pefakit® APC-R Factor V Leiden Controls' and the control plasmas included in the predicate device 'COATEST® APC™ RESISTANCE V' are equivalent in terms of intended use, safety of use and overall qualitative characteristics.



Reto Schöni, Ph. D.

September 30, 2004



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 2004

Pentapharm Ltd.
c/o Ms. M. Elisabeth Bierman
Morgan, Lewis & Bockius LLP.
1111 Pennsylvania Avenue., NW
Washington DC 20004

Re: k042760
Trade/Device Name: Pefakit® APC-R Factor V Leiden Controls
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: December 7, 2004
Received: December 9, 2004

Dear Ms. Bierman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

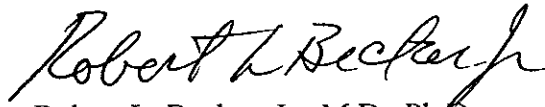
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, reading "Robert L. Becker, Jr." in a cursive style.

Robert L. Becker, Jr., M.D., Ph.D.

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042760

Device Name: **Pefakit® APC-R Factor V Leiden Controls**

Indications For Use:

The device is a box containing lyophilized pooled plasmas from donors genotyped for the factor V Leiden mutation (FV: Q506) to be reconstituted with water by the user. Controls contain pooled plasmas of either donors with heterozygous FV:Q506 mutation or normal wild-type pattern. These controls are intended to be used for quality assurance in connection with the IVD device 'Pefakit® APC-R Factor V Leiden'.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Stephen B. Butler
Division Sign Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K042760

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